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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,575	08/14/2001	Salih J. Wakil	D6374CIP	9113

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EXAMINER	
PARAS JR, PETER	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 12/12/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)	
Office Action Summary	09/929,575	WAKIL ET AL.	
	Examiner	**Art Unit**	
	Peter Paras, Jr.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, drawn to methods that encompass administering an inhibitor of acetyl-CoA carboxylase 2 to an individual that has diabetes, classified in class 514, subclass 44.

II. Claims 1-4, drawn to drawn to methods that encompass administering an inhibitor of acetyl-CoA carboxylase 2 to an individual that has obesity, classified in class 424, subclass 94.1.

III. Claims 7-14 and 20-21 drawn to a transgenic mouse comprising a mutation in an endogenous ACC2 gene and a cell line obtained from the same mouse, classified in classes 800 and 435, subclasses 18 and 325.

IV. Claim 15, drawn to a method of screening for an inhibitor of acetyl-CoA carboxylase 2 isoform activity comprising administering potential inhibitors to a wild-type mouse, classified in class 800, subclass 9.

V. Claims 16-17, drawn to drawn to an inhibitor of acetyl-CoA carboxylase 2, and a pharmaceutical composition comprising the same inhibitor of acetyl-CoA carboxylase 2 are unclassifiable as the inhibitor is unknown.

VI. Claim 18, drawn to a method of obtaining a purified preparation of acetyl-CoA carboxylase-1 protein, classified in class 530, subclass 412.

VII. Claim 19, drawn to a method of obtaining antibodies against acetyl-CoA carboxylase-2, classified in class 800, subclass 4.

VIII. Claims 22-23, drawn to a method of screening agonists and antagonists of ACC2 using a cell line, classified in class 435, subclass 7.1.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper between Groups I, II, IV, VI, VII, and VIII because their methods appear to constitute patentably distinct inventions, each with a distinct purpose and further comprising distinct methodologies and using different products. For example the method of Group IV requires the use of a wild type mouse for identifying potential inhibitors of acetyl-CoA carboxylase 2, the method of Group I can be used to treat an individual having diabetes, the method of Group II can be used to treat an individual having obesity, the method of Group VI can be used to purify a protein, the method of Group VII can be used produce antibodies, and the method of Group VIII can be used to screen for agonists and antagonists of ACC2 in a cell line *in vitro*. As such the methods of Groups I, II, IV, VI, VII, and VIII have distinct purposes and are not capable of use together. The methods I, II, IV, VI, VII, and VIII of also require the use of materially different products having different chemical structures. For example, the method of Group IV requires the use of a wild type mouse while the method of Group VII requires a transgenic mouse and the method of Group requires an inhibitor of acetyl-CoA carboxylase 2. Because these inventions are distinct for the reasons given above

and a separate search is required for each of Groups II, IV, V, VI, and VII restriction for examination purposes as indicated is proper.

Inventions III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects. Moreover, the products of Inventions III and V have different chemical structures and can be used in methods that require different reagents and technical considerations. The transgenic mouse of Invention III can be used as a model of disease while the inhibitor of Invention V can be used to inhibit the function of acetyl-CoA carboxylase 2. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate search requirement, restriction for examination purposes as indicated is proper.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different functions. The transgenic mouse of Invention IIII can be used in methods that are different from the method of Invention IV, which would require the use of different reagents while the method of Invention II can be practiced with products that have different chemical structures from the transgenic mouse of Invention III. For example,

the transgenic mouse of Invention IIII can be used as a model of disease and can also be used to screen for potential therapeutic agents while the method of Invention IV requires the use of a wild type mouse. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter which requires a separate search, restriction for examination purposes as indicated is proper.

Inventions III and I-II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different functions. The transgenic mouse of Invention IIII can be used in methods that are different from the methods of Inventions I-II, which would require the use of different reagents while the methods of Inventions I-II can be practiced with products that have different chemical structures from the transgenic mouse of Invention III. For example, the transgenic mouse of Invention III can be used as a model of disease and can also be used to screen for potential therapeutic agents while the methods of Inventions I-II can be used to treat different diseases, such as diabetes and obesity, respectively. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter which requires a separate search, restriction for examination purposes as indicated is proper.

Inventions III and VI-VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1)

the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the transgenic mouse of Invention I can be used in materially different processes than the processes of Inventions VI and VIII. For example, the transgenic mouse of Invention I can represent a model of disease and can be used in a method for screening potential therapeutic agents while the methods of Inventions VI and VII can be used to obtain purified ACC-1 or to obtain antibodies against ACC-2, respectively. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter that requires a separate search, restriction for examination purposes as indicated is proper.

Inventions III and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and different effects. For example the transgenic mouse of Invention III can be used as a model of disease while the method of Invention VIII can be used screen for compounds *in vitro*.

Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case inhibitor of

Invention V can be used in a materially different process than the process of Invention IV. For example, the inhibitor of invention V can be used to generate antibodies in an animal. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter that requires a separate search, restriction for examination purposes as indicated is proper.

Inventions V and I-II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the inhibitor of Invention V can be used in a materially different process than the processes of Inventions I-II. For example, the inhibitor of Invention V can be used to generate antibodies in an animal.

Inventions V and VI-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects. The inhibitor of Invention V can be used in methods that are different from the methods of Inventions V-VIII, which require materially different reagents and different technical considerations. The methods of Inventions V-VIII can be practiced with reagents that have different chemical structures

from the inhibitor of Invention V. For example, the method of Invention VI can be used to isolate a protein and the method of Invention VII can be used to produce antibodies while the inhibitor of Invention V can be used to suppress the function of acetyl-CoA carboxylase. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter that requires a separate search, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703) 308-4242 and (703) 305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (703) 305-3388.

Peter Paras, Jr.
Art Unit 1632

Peter Paras
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